STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY

IN RE:	)	
	)	
L & P CORPORATION	)	
dba WHARF PHARMACY	)	Complaint No. 2014-006377
Permit No: 003121	)	
2175 W. Terra Lane	)	
O'Fallon, MO 63366	)	

SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND L & P CORPORATION dba WHARF PHARMACY

Come Now L & P Corporation dba Wharf Pharmacy ("Respondent" or the "Pharmacy") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its

permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 003121, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo[1], for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. L & P Corporation dba Wharf Pharmacy ("Respondent" or "the Pharmacy") is permitted by the Board as a pharmacy, permit number Permit No. 003121. The Pharmacy is located at 2175 W. Terra Lane, O'Fallon, MO 63366.

3. At all times relevant herein, Andrew Palans was the pharmacist-in-charge (the "PIC") of the Pharmacy.

4. David Payton ("Payton") is a licensed pharmacist under the laws of the State of Missouri who at all times relevant hereto worked as a part-time pharmacist at the Pharmacy.

[1] All statutory references are to the 2000 Revised Statutes of Missouri, (Cum. Supp. 2013), unless otherwise stated.

Violations relating to fentanyl drugs

5. On or around October 16, 2014, the Board received a complaint (the "complaint") from D.FS stating that Schnucks Pharmacy #106 in Ballwin, Missouri ("Schnucks Pharmacy") had refused to fill a prescription for Fentanyl Citrate 1600mcg that she presented to Schnucks Pharmacy on September 12, 2014.

6. Schnucks Pharmacy refused on the basis that it was too soon to refill the prescription because it had been filled on September 10, 2014, by Respondent.

7. The complaint further stated that a claim had been submitted to D.FS's insurance by Respondent on September 8, 2014, for Subsys SL Spray 10's 100mcg allegedly prescribed by Dr. Philip Dean even though she had never taken the drug or seen the physician.

8. D.FS had not requested that Respondent fill any of her prescriptions since on or about May 14, 2014.

9. The last prescription D.FS requested be filled by Respondent on or about May 14, 2014, was prescription no. 691979 originally written by Dr. Brian Smith, Western Anesthesiology Associates, 5401 Veteran's Memorial Parkway, Suite 102, St. Peters, Missouri, on March 4, 2014 for Actiq 1600mcgs.[2]

10. Fentanyl is a Schedule II controlled substance. §195.017.4(2)(i), RSMo.

11. Actiq only can be prescribed by physicians who are enrolled in the Federal Drug Administration's Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy ("TIRF REMS") program, the goals of which are to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors.

[2] Actiq is a brand name for fentanyl citrate.

12. Dr. Brian Smith's enrollment in the TIRF REMS program had expired sometime prior to or on May 14, 2014.

13. Through telephone conversations with Dr. Brian Smith's office, PIC Palans had direct knowledge that Dr. Smith's enrollment in the TIRF REMS program had expired, but he proceeded to fill the prescription for Fentanyl Citrate for D.FS on the belief that Dr. Smith intended to re-enroll in the program.

14. D.FS's insurance provider rejected the claim submitted by PIC Palans for payment of Fentanyl Citrate dispensed to D.FS on the grounds that Dr. Smith was not enrolled in the TIRF REMS program.

15. The total cost of the medication was approximately $6,000.00.

16. PIC Palans sent an invoice to D.FS's last known address on or around August 7, 2014, for the approximate $6,000.00 charge, but the invoice was returned to Respondent as "undeliverable" on August 19, 2014, because D.FS had moved and no longer lived at that address.

17. On or about August 7, 2014, PIC Palans generated two prescriptions for Fentanyl Citrate 1600 mcg LPOP, one under prescription no. 687309 with Dr. Brian Smith, Western Anesthesiology Associates, 5401 Veteran's Memorial Parkway, Suite 102, St. Peters, Missouri, as prescribing physician and the other under prescription no. 687310 with Dr. Stephen Schmidt, Western Anesthesiology Associates, 5401 Veteran's Memorial Parkway, Suite 102, St. Peters, Missouri, as prescribing physician.

18. Both prescriptions later were canceled.

19. During a visit to the Pharmacy on January 8, 2015, by Board Inspector Dan Vandersand, Inspector Vandersand was unable to locate either prescription on file at the Pharmacy.

20. On or about August 10, 2014, PIC Palans submitted a claim to D.FS's insurance provider for Fentanyl Citrate 1600 mcg LPOP under prescription no. 692010.

21. Respondent did not have prescription no. 692010 on file on October 23, 2014.

22. Respondent was paid $3,371.02 in insurance proceeds on the August 10, 2014, claim.

23. D.FS never received this prescription medication from Respondent.

24. On or about September 8, 2014, PIC Palans submitted a claim to D.FS's insurance provider for Subsys SL Spray 10's[3] under prescription no. 691484 prescribed by Dr. Philip Dean.

25. Subsys spray is a Schedule II controlled substance. §195.017.4(2)(i), RSMo.

26. Respondent was paid $993.56 in insurance proceeds on the September 8, 2014, claim.

27. D.FS never received Subsys SL Spray from Respondent, was never prescribed this medication and had never seen Dr. Dean.

28. In an October 27, 2014, written response from PIC Palans to Inspector Vandersand, PIC Palans indicated that he received a prescription for Subsys SL Spray as he was updating information for D.FS, and accidentally filed it under D.FS's name.

29. The claim for Subsys SL Spray was not reversed with D.FS's insurance provider until December 12, 2014, with the reason for the reversal noted as "Patient Name Different."

30. On or around September 10, 2014, PIC Palans submitted a claim to D.FS's insurance provider for Fentanyl Citrate 1600 mcg LPOP under prescription no. 692010.

31. Records show the prescribing physician of prescription no. 692010 as Dr. Richard Divalerio, 3009 N. Ballas Road, Saint Louis, MO 63131.

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[3] Subsys SL spray is a brand name for fentanyl sublingual spray.

32. On January 8, 2015, Inspector Vandersand located a document at the Pharmacy that purported to be prescription no. 692010. It consisted of a sticker bearing a date of September 10, 2014, on a piece of paper with "RX" letterhead indicating that Philip Dean was the prescribing physician. Handwritten on the face of the purported prescription were the words "put with RX #671979."

33. PIC Palans stated to Inspector Vandersand on October 23, 2014, that he ran through prescription no. 692010 on D.FS.'s insurance knowing that it would be rejected at whichever pharmacy she was using and that he would then be able to get her current address and phone number so that he could speak with her about her unpaid charge at the Pharmacy.

Failure to comply with TIRF REMS

34. According to 21 U.S.C. § 355(p)(1)(A)-(B)[4]:

> (p) Risk evaluation and mitigation strategy
>
> (1) In general
> A person may not introduce or deliver for introduction into interstate commerce a new drug if--
> (A)(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 353(b) of this title; or
> (ii) the application for such drug is approved under section 262 of Title 42; and
> (B) a risk evaluation and mitigation strategy is required under section 355-1 of this title with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 355-1 of this title, including requirements regarding assessments of approved strategies.

35. 21 U.S.C. § 355-1(f)(3) provides:

> (f) Providing safe access for patients to drugs with known serious risks that would otherwise be unavailable.
>
> (3) Elements to assure safe use

[4] All statutory references are to the United States Code (2012), as supplemented, unless otherwise indicated.

> The elements to assure safe use under paragraph (1) shall include 1 or more goals to mitigate a specific serious risk listed in the labeling of the drug and, to mitigate such risk, may require that--
> (A) health care providers who prescribe the drug have particular training or experience, or are specially certified (the opportunity to obtain such training or certification with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an on-line course or via mail) as approved by the Secretary at reasonable cost to the provider);
> (B) pharmacies, practitioners, or health care settings that dispense the drug are specially certified (the opportunity to obtain such certification shall be available to any willing provider from a frontier area);

36. The application for Actiq was approved under 21 U.S.C. § 355(b) and is subject to 21 U.S.C. § 353(b).

37. In the section of the TIRF REMS entitled "Elements to Ensure Safe Use," it states that TIRF medicines will only be dispensed by certified pharmacies and that to become certified each pharmacy must be enrolled in the TIRF REMS access program.

38. An authorized pharmacist completing the application on behalf of a pharmacy must acknowledge the following:

> (h) I understand that TIRF medicines will not be dispensed without verifying through our pharmacy management system that the prescriber and pharmacy are enrolled and active, and that the patient has not been inactivated in the program.
>
> Section II.B.2.d(h) of the TIRF REMS.

39. By dispensing Fentanyl Citrate to D.FS on May 14, 2014, knowing that Dr. Brian Smith's TIRF REMS enrollment was no longer active, PIC Palans failed to comply with the approved TIRF REMS and with 21 U.S.C. § 355-1(f)(3)(B), and therefore, violated 21 U.S.C. § 355(p)(1)(A)-(B).

Misbranding

40. Section 196.015(1)-(2), RSMo prohibits misbranding of drugs in the State of Missouri, to wit:

> The following acts and the causing thereof within the state of Missouri are hereby prohibited:
>
> > (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
> >
> > (2) the adulteration or misbranding of any food, drug, device, or cosmetic;

41. Misbranding of a drug under Missouri law is defined in § 196.100.1, RSMo, which states in pertinent part:

> 1. Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.

42. Pursuant to 21 U.S.C. §352(y) of the Federal Food, Drug and Cosmetic Act, as amended, a drug subject to approved risk evaluation and mitigation strategy is misbranded when:

> (y) Drugs subject to approved risk evaluation and mitigation strategy.
>
> If it is a drug subject to an approved risk evaluation and mitigation strategy pursuant to section 355(p) of this title and the responsible person (as such term is used in section 355-1 of this title) fails to comply with a requirement of such strategy provided for under subsection (d), (e), or (f) of section 355-1 of this title.

43. Federal law also prohibits:

> (a) The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded.

(b) The adulteration or misbranding of any . . . drug . . . in interstate commerce.

21 U.S.C. § 331(a)-(b).

44. By dispensing Fentanyl Citrate to D.FS on May 14, 2014, knowing that Dr. Brian Smith's TIRF REMS enrollment was no longer active, PIC Palans failed to comply with the approved TIRF REMS and with 21 U.S.C. § 355-1(f)(3)(B). His actions constitute misbranding in violation of §§ 196.100, .015, RSMo, and 21 U.S.C. §§ 331, 352(y).

Inaccurate records

45. According to § 338.100, RSMo:

1. Every permit holder of a licensed pharmacy shall cause to be kept in a uniform fashion consistent with this section a suitable book, file, or electronic record-keeping system in which shall be preserved, for a period of not less than five years, the original or order of each drug which has been compounded or dispensed at such pharmacy, according to and in compliance with standards provided by the board, and shall produce the same in court or before any grand jury whenever lawfully required. A licensed pharmacy may maintain its prescription file on readable microfilm for records maintained over three years. After September, 1999, a licensed pharmacy may preserve prescription files on microfilm or by electronic media storage for records maintained over three years. The pharmacist in charge shall be responsible for complying with the permit holder's record-keeping system in compliance with this section. Records maintained by a pharmacy that contain medical or drug information on patients or their care shall be considered as confidential and shall only be released according to standards provided by the board. Upon request, the pharmacist in charge of such pharmacy shall furnish to the prescriber, and may furnish to the person for whom such prescription was compounded or dispensed, a true and correct copy of the original prescription. The file of original prescriptions kept in any format in compliance with this section, and other confidential records, as defined by law, shall at all times be open for inspection by board of pharmacy representatives. Records maintained in an electronic recordkeeping system shall contain all information otherwise required in a manual recordkeeping system. Electronic records shall be readily retrievable. Pharmacies may electronically maintain the original prescription or prescription order for each drug and may electronically annotate any change or alteration to a prescription record in the electronic record-keeping system as authorized by law; provided however, original

written and faxed prescriptions shall be physically maintained on file at the pharmacy under state and federal controlled substance laws.

46. 20 CSR § 2220-2.080(1)-(3) states:

(1) In lieu of a non-electronic (manual) record-keeping system, a pharmacy may elect to maintain an electronic data processing (EDP) record keeping-system. All information concerning the compounding, dispensing, or selling by a pharmacy of any drug, device, or poison pursuant to a lawful prescription which is entered into an EDP system at any pharmacy shall be entered only by a licensed pharmacist or by a technician or intern pharmacist under the direct supervision and review of a licensed pharmacist. Prior to dispensing, a pharmacist shall personally verify the accuracy of prescription data entered into the EDP for each original prescription. The EDP system shall comply with all applicable state and federal controlled substance laws and regulations.

(2) EDP systems shall comply with the requirements of section 338.100, RSMo, and shall be capable of storing and retrieving the following information concerning the original filling or refilling of any prescription:

(A) A unique, sequential prescription label number;
(B) If applicable, a unique readily retrievable identifier;
(C) Date the prescription was prescribed;
(D) The date the prescription was initially filled and the date of each refill;
(E) Patient's full name, or if an animal, the species and owner's name;
(F) Patient's address or animal owner's address when a prescription prescribes a controlled substance;
(G) Prescriber's full name;
(H) Prescriber's address and Drug Enforcement Administration (DEA) number when a prescription specifies a controlled substance;
(I) Name, strength and dosage of drug, device or poison dispensed and any directions for use;
(J) Quantity originally dispensed;
(K) Quantity dispensed on each refill;
(L) Identity of the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing on each original prescription;
(M) Identity of the pharmacist responsible for reviewing the final product prior to dispensing on each original and refill prescription, if different from the pharmacist verifying prescription data;
(N) The number of authorized refills and quantity remaining;
(O) Whether generic substitution has been authorized by the prescriber;

> (P) The manner in which the prescription was received by the pharmacy (e.g., written, telephone, electronic, or faxed); and
> (Q) Any other change or alteration made in the original prescription based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug.
>
> (3) The information specified in section (2) shall be required and recorded in the EDP system prior to dispensing by a pharmacist or pharmacy.

47. Respondent violated §338.100.1, RSMo and 20 CSR § 2220-2.080(1)-(3) by failing to maintain prescription nos. 691484, 687309, 687310 and 692010 and by entering false data relating to said prescriptions into its electronic data processing record keeping system.

No Immunization Protocol

48. On or about October 23, 2014, Inspector Vandersand conducted a routine inspection at the Pharmacy, and a follow-up inspection on October 29, 2014.

49. During his inspections, he reviewed Respondent's vaccination administration records (the "VAR") for 2013 and 2014.

50. The VAR showed that Payton had administered 23 vaccines in 2013 and 21 vaccines in 2014, as of October 23, 2014, at the Pharmacy.

51. Respondent did not have an immunization protocol signed by an authorizing physician and by Payton for 2013 or 2014.

52. Dr. Kevin Weikart "signed off" on the administrations by signing his name to the bottom of a computer-generated listing of patients who had received vaccinations at the Pharmacy which he returned to the Pharmacy after signing.

53. Missouri law gives a licensed pharmacist the authority to give immunizations, to wit:

> 1. The "practice of pharmacy" means . . . the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical

> prescription orders and administration of viral influenza, pneumonia, shingles and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by a physician for a specific patient as authorized by rule; . . .
>
> § 338.010.1, RSMo.

54. However, Missouri law requires very specific requirements to be met in order for the pharmacist to be authorized to give immunizations under immunization protocol. These requirements are contained in 20 CSR § 2220-6.050, which provides:

> (1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine.
>
> > (A) A pharmacist shall administer vaccines in accordance with treatment guidelines established by the Centers for Disease Control (CDC) and in accordance with manufacturer's guidelines, provided that a pharmacist shall not administer vaccines to persons under twelve (12) years of age.
> >
> > (B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirement.
>
> * * *
>
> (4) Pharmacist Qualifications. A pharmacist who is administering a vaccine authorized by Chapter 338, RSMo, must:
>
> > (A) Hold a current unrestricted license to practice pharmacy in this state;
> >
> > (B) Hold a current cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;
> >
> > (C) Successfully complete a certificate program in the administration of vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy;

(D) Maintain documentation of the above certifications;

(E) Complete a minimum of two (2) hours (0.2 CEU) of continuing education as defined per calendar year related to administration of vaccines. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal.

(F) Provide documentation of subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering vaccines; and

(G) On a yearly basis prior to administering vaccines, establish a new protocol with the authorizing physician and notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), (E), and (F) of this section.

(5) Administration by Written Protocol with a Missouri Licensed Physician.

(A) A pharmacist may enter into a written protocol with a physician for the administration of vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the vaccine. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures . . .

(B) The protocol, and any subsequent amendments or alterations, shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from

the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

55. By giving immunizations without a written protocol signed by Payton and an authorizing physician, Payton violated § 338.010.1, RSMo and 20 C.S.R. § 2220-6.050(1), (4)(F)-(G), (5)(A)-(B).

Violations relating to Hormone Replacement Therapy Prescriptions

56. During his October 29, 2014, follow-up inspection at the Pharmacy relating to the Pharmacy's lack of immunization protocol, PIC Palans informed Inspector Vandersand that Olivia Joseph, a chiropractic physician, prescribed progesterone and testosterone products for patients and Dr. Weikart "signed off" on the purported prescriptions as the collaborating physician.

57. As with the administrations of vaccinations, Dr. Weikart "signed off" on the purported prescriptions by placing his name at the bottom of the last page of a listing of a group patients contained in a computer-generated printout of prescriptions filled between specific dates at the Pharmacy.

58. Dr. Weikart "signed off" on the purported prescriptions after the medications were dispensed.

59. Dr. Weikart never saw any of the patients for whom he "signed off" on the purported prescriptions as the collaborating physician.

60. Dr. Weikart did not keep a chart on any of the patients for whom he "signed off" on purported prescriptions as the collaborating physician.

61. Olivia Joseph has never spoken to Dr. Weikart about any of the purported prescriptions.

62. Respondent did not obtain authorization to dispense the purported prescriptions from Dr. Weikart or any other authorized prescriber prior to the medication being dispensed at the Pharmacy.

63. From March 1, 2013, to June 1, 2013, at least 45 prescriptions for hormone replacement therapy containing testosterone were filled by Respondent with Olivia Joseph listed as prescriber under Drug Enforcement Agency ("DEA") registration no. AJ5821877.

64. During that same time period, at least 42 prescriptions for hormone replacement therapy without testosterone were filled by Respondent listing Olivia Joseph as the prescriber.

65. The Pharmacy's DEA registration no. is AW5821877.

66. On or about November 6, 2014, Inspector Vandersand requested a copy of all prescriptions filled under Olivia Joseph's name and in response to that request, PIC Palans sent Inspector Vandersand a computer printout of 242 prescriptions from January 1, 2008, to November 6, 2014, showing the prescriber as "Olivia Joseph-Weikart."

67. All 242 prescriptions on the printout were for hormone replacement therapy.

68. Of these 242 prescriptions, at least 234 of them were for hormone replacement therapy containing testosterone with Olivia Joseph listed as prescriber under DEA registration no. BW09477014.

69. Of these 242 prescriptions, at least eight of them were for hormone replacement therapy without testosterone with Olivia Joseph listed as prescriber.

70. PIC Palans advised Inspector Vandersand that he combined all of Olivia Joseph's prescriptions in his computer system under "Joseph-Weikart" on or around November 6, 2014.

71. The address listed on the printout was 111 O'Fallon Commons, O'Fallon, MO 63366, which is Olivia Joseph's address.

72. Dr. Weikart's DEA registration no. is BW09477014.

73. Testosterone is a Schedule III controlled substance under §195.0176(5)(z), RSMo.

74. Chiropractors do not have prescribing authority in the State of Missouri.

Misbranding

75. Section 196.015(1)-(2), RSMo prohibits misbranding of drugs in the State of Missouri, to wit:

> The following acts and the causing thereof within the state of Missouri are hereby prohibited:
>
> > (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
> >
> > (2) the adulteration or misbranding of any food, drug, device, or cosmetic;

76. Misbranding of a drug under Missouri law is defined in § 196.100.1, RSMo, which states in pertinent part:

> 1. Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.

77. A legend drug is misbranded under 21 U.S.C. §353(b)(1) of the Federal Food, Drug and Cosmetic Act, as amended, under the following circumstances:

> (b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws
>
> > (1) A drug intended for use by man which –
> >
> > > (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, is not safe for use except under the

> supervision of a practitioner licensed by law to administer such drug; or
>
> (B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;
>
> shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

78. Federal law also prohibits:

> (a) The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded.
>
> (b) The adulteration or misbranding of any . . . drug . . . in interstate commerce.

21 U.S.C. § 331(a)-(b).

79. Respondent's dispensing of drugs, including controlled substances, without valid prescriptions constitutes misbranding in violation of §§ 196.100, .015, RSMo, and 21 U.S.C. §§ 331, 353.

Wrongful dispensing due to invalid prescriptions

80. According to § 338.056.3, RSMo, prescriptions written in the State of Missouri must comply with the requirements of § 338.056.2.

81. § 338.056.2 states that:

2. A pharmacist who receives a prescription for a brand name drug may, unless requested otherwise by the purchaser, select a less expensive generically equivalent product under the following circumstances:
(1) If a written prescription is involved, the prescription form used shall have two signature lines at opposite ends at the bottom of the form. Under the line at the right side shall be clearly printed the words: "Dispense as Written". Under the line at the left side shall be clearly printed the words "Substitution Permitted". The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the prescriber on one of these lines;
(2) If an oral prescription is involved, the practitioner or the practitioner's agent, communicating the instructions to the pharmacist, shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug may be substituted. The pharmacist shall note the instructions on the file copy of the prescription.

82. 20 CSR § 2220-2.018 also provides:

(1) To be valid for purposes of dispensing, a prescription shall conform to all requirements of sections 338.056 or 338.196, RSMo, and shall contain the following information:

(A) The date of prescribing;
(B) The name of the patient(s), or if an animal, species and owner's name;
(C) The prescriber's name, if an oral prescription, or written or electronic signature if a written, faxed, or an electronically transmitted prescription. Electronic signatures shall comply with all applicable provisions of 20 CSR 2220-2.085;
(D) Name, strength and dosage of drug, device or poison prescribed and the directions for use;
(E) The number of refills, if applicable;
(F) The quantity prescribed in weight, volume, or number of units;
(G) An indication of whether generic substitution has been authorized by the prescriber, as required by section 338.056, RSMo;
(H) Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug;
(I) The address of the prescriber and the patient when the prescription is for a controlled substance;
(J) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and
(K) Controlled substance prescriptions shall also comply with all requirements of federal and state controlled substance laws.

83. PIC Palans and/or other pharmacists at the Pharmacy violated § 338.056.2-3, RSMo, and 20 CSR § 2220-2.018(1) by dispensing medication under prescriptions that did not meet the requirements for valid prescriptions in Missouri, including but limited to not having two signature lines with the words: "Dispense as Written" under the right line and the words "Substitution Permitted" under the left line, not containing the signature of an authorized prescriber on one of those lines, and not having the prescriber's DEA number when controlled substances were involved.

Wrongful dispensing due to lack of patient-practitioner relationship

84. According to 20 CSR § 2220-2.020(11):

> (11) Prescriptions processed by any classification of licensed pharmacy must be provided by a practitioner licensed in the United States authorized by law to prescribe drugs and who has performed a sufficient physical examination and clinical assessment of the patient. A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.

85. PIC Palans and/or other pharmacists at the Pharmacy violated 20 CSR § 2220-2.020(11) by dispensing prescription drugs for patients for whom he knew or reasonably should have known had neither been physically examined nor clinically assessed by Dr. Weikart and with whom Dr. Weikart had no patient-practitioner relationship.

JOINT CONCLUSIONS OF LAW

86. By virtue of its pharmacist in charge creating false prescriptions, submitting false claims to insurance, failing to comply with TIRF REMS programs, filling invalid and unlawful prescriptions, wrongfully dispensing drugs, making and entering false data relating to prescriptions into its record keeping system and misbranding drugs, and its pharmacist giving unlawful

immunizations, the pharmacy knew or should have known that its employees had violated pharmacy laws and rules.

87. Missouri law provides:

> (O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.
>
> 20 CSR § 2220-2.010(1)(O).

88. Cause exists to discipline Respondent's permit to operate a pharmacy under §338.210.5, RSMo, which provides:

> 5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

89. Respondent's conduct is also cause for disciplinary action against its pharmacy permit under §338.055.2, (5), (6), and (13), RSMo, which provides:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
>
> * * *
>
> (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
>
> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
>
> * * *

(13) Violation of any professional trust or confidence;

90. Cause exists to discipline Respondent's permit under section 338.055.2(5), RSMo in that Respondent's conduct as alleged herein constitutes incompetency, misconduct, gross negligence, dishonesty, fraud and/or misrepresentation in the performance of the functions or duties of a licensed pharmacy.

91. Cause exists to discipline Respondent's permit under section 338.055.2(6), RSMo in that Respondent's conduct as alleged herein violated, assisted or enabled persons to violate the provisions of Chapter 338, and rules and regulations adopted thereunder.

92. Cause exists to discipline Respondent's permit under section 338.055.2(13), RSMo in that Respondent's conduct as alleged herein constitutes a violation of professional trust or confidence.

JOINT AGREED DISCIPLINARY ORDER

A. Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of §621.045.4(3), RSMo. Respondent's pharmacy permit, number 003121 shall be placed on **PROBATION for a period of THREE (3) YEARS** ("disciplinary period"). The terms of discipline shall be:

The following terms apply for the entire disciplinary period.

1. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.

2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and

state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

3. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by the Respondent, and the individuals' current home addresses and telephone numbers.

4. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

5. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.

6. Respondent shall not serve as an intern training facility for interns.

7. Respondent shall select an independent pharmacist consultant for the purpose of reviewing and insuring the pharmacy's compliance with all applicable laws and regulations. The consultant shall be a Missouri licensed pharmacist whose license is current and not subject to disciplinary action by the Board. Within thirty (30) days of the beginning of probation Respondent shall submit documentation and credentials of its chosen consultant to the Board office for approval. Within thirty (30) days of the beginning of probation the said consultant shall visit the pharmacy, evaluate and provide corrective actions to remedy the issues outlined in this Agreement, conduct a review for compliance with all applicable laws and regulations, and submit a written report to the Board office within thirty (30) days of the visit. The consultant's report shall include the suggested

corrective actions, a timeline for the pharmacy to complete such corrective actions, items/areas reviewed for compliance with applicable laws and regulations during the visit, any deficiencies noted, and a plan to correct any deficiencies noted. The consultant shall then conduct visits and provide ongoing reports to the Board office on a six (6) month cycle. All consultant reports are due at the Board office within thirty (30) days of the consultant's visit to the pharmacy. The consultant shall be hired at Respondent's expense.

8. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

9. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

10. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

B. Upon the expiration of said discipline, Respondent's license as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

C. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

D. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

E. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

F. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which

may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____ **REQUESTS**

AP **DOES NOT REQUEST**

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT TO OPERATE AS A PHARMACY.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect 15 days after the document is signed by the Board's Executive Director.

RESPONDENT

L & P CORPORATION
dba WHARF PHARMACY

By: _____
As Authorized Agent for
L & P CORPORATION
dba WHARF PHARMACY

Printed: _____

Date: 7/11/16

PETITIONER

MISSOURI BOARD OF
PHARMACY

By: _____
KIMBERLY GRINSTON
Executive Director

Date: 7/28/16

NEWMAN, COMLEY & RUTH P.C.

By: _____
Alicia Embley Turner #48675
601 Monroe, Suite 301
P.O. Box 537
Jefferson City, MO 65102-0537
Telephone: (573) 634-2266
Fax: (573) 636-3306
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Attorneys for Missouri Board of Pharmacy